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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/069,228 | 04/27/98 | FLOWMAN | 234/118 |

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HM22/0607

EXAMINER
HOLLERAN, A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1642 | |

DATE MAILED: 06/07/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/069,228

Applicant(s)
Plowman et al.

Examiner
Anne Holleran

Group Art Unit
1642



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-22 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9, drawn to polynucleotides encoding ALK-7 polypeptides and a recombinant cell comprising said polynucleotides, classified in classes 536 and 435 subclasses 23.5 and 325, respectively.
 - II. Claims 10-12, drawn to ALK-7 polypeptides, classified in class 530, subclass 350.
 - III. Claims 13 and 14, drawn to antibody or antibody fragments having specific binding affinity to ALK-7 polypeptides and a hybridoma which produces said antibody, classified in classes 530 and 435, subclasses 387.1 and 338, respectively.
 - IV. Claims 15 and 16, drawn to methods of identifying a substance capable of modulating ALK-7 activity, classified in class 435, subclass 7.1.
 - V. Claims 17-20, drawn to methods of treatment with a modulator of ALK-7 activity, classified in class 514, subclass 2.
 - VI. Claims 21 and 22, drawn to kits comprising a modulator of ALK-7 activity, classified in class 514, subclass 2.
2. The inventions are distinct, each from the other, for the following reasons:

Each of inventions I, II, III and VI is directed to a separate and distinct product. Each of inventions I, II, III and VI would be expected to have distinct morphological, functional, chemical

and physical properties as evidenced by divergent classification. It is possible to separately manufacture, use and sell the products as claimed. Furthermore, these products are patentable over each other (though they may each be unpatentable because of the prior art).

Each of inventions IV and V is directed to a separate and distinct process. Each of the processes are distinct both physically and functionally, require different steps and make or use different products. Invention IV is drawn to *in vitro* methods and invention V is drawn to *in vivo* methods. In addition, invention IV is used to identify the product, modulators of ALK-7 activity, that is used in invention V.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of invention VI could be used in an *in vitro* assay method, a materially different process than that of invention V.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and recognized divergent subject matter and because searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

4. A telephone call to Mr. Berkman on 14 May 1999 did not result in an election to prosecute an invention group.

5. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

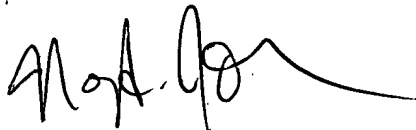
7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Ms. Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzler, Ph.D. can be reached at (703) 308-4310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

AH

Anne Holleran
Patent Examiner
June 3, 1999



Nancy A Johnson
Primary Examiner